

Declaration of Conformity – European Union  
Infant resuscitators and accessories

Doc. No: REG-56

Revision: M

<b>Manufacturer:</b>	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand
<b>Authorised Representative:</b>	Fisher & Paykel Healthcare Ltd Unit 16, Cordwallis Park, Clivemont Road, Maidenhead SL6 7BU, United Kingdom
<b>Product Category:</b>	Gas powered pulmonary resuscitators
<b>Medical Device Family:</b>	Infant resuscitators and accessories
<b>Conformity Assessment Route:</b>	Annex II (for class IIa and above) Annex VII (for class I)
<b>Validity of this declaration:</b>	This Declaration of Conformity, for each model listed, is valid from the start date recorded against the model and for as long as the model is listed on the DoC. When a model is no longer covered by the DoC, it is transferred to a Discontinued Medical Devices list and an end date recorded against it.
<p>We, the manufacturer, declare under our sole responsibility that the stated medical devices meet the transposition into national law, the provisions of Council Directive 93/42/EEC concerning medical devices. All supporting documentation is retained by the manufacturer.</p>	
<b>Notified Body:</b>	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Germany
<b>Identification number:</b>	CE 0123

Approval

Name	Title	Signature	Date and Location
Adele Bindon	Regulatory Affairs Manager		Auckland, NZ 12 May 15

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REF	Product Description	Class	GMDN Code	MDD rule number	Start Date
900IW130D	NEOPUFF MODULE DAN	IIb	13366	Rule 9 scl 2	14/Dec/1999
900IW130E	NEOPUFF INFANT RESUSCITATOR	IIb	13366	Rule 9 scl 2	13/May/1998
900IW130F	NEOPUFF MODULE FRE	IIb	13366	Rule 9 scl 2	05/Feb/1999
900IW130G	NEOPUFF MODULE GER	IIb	13366	Rule 9 scl 2	12/Aug/1998
900IW130L	NEOPUFF MODULE ITA	IIb	13366	Rule 9 scl 2	17/Nov/1998
900IW130M	NEOPUFF MODULE FIN	IIb	13366	Rule 9 scl 2	14/Dec/1999
900IW130N	NEOPUFF MODULE DUTCH	IIb	13366	Rule 9 scl 2	05/Feb/1999
900IW130S	NEOPUFF MODULE SPA	IIb	13366	Rule 9 scl 2	09/Mar/1999
900IW130T	NEOPUFF MODULE POR	IIb	13366	Rule 9 scl 2	14/Dec/1999
900IW130V	NEOPUFF MODULE NOR	IIb	13366	Rule 9 scl 2	23/Aug/1999
900IW130W	NEOPUFF MODULE SWE	IIb	13366	Rule 9 scl 2	21/Dec/1998
900RD008	GAS SUPPLY LINE SHORT 10BX	IIa	37498	Rule 2	12/Dec/2002
900RD009	GAS SUPPLY LINE LONG 10BX	IIa	37498	Rule 2	12/Dec/2002
900RD010	S/USE RESUS KIT W/O MASK 10BX	IIa	37498	Rule 2	12/Dec/2002
900RD014-10	S/USE RESUS KIT W/42mm MSK(10)	IIa	37498	Rule 2	24/Oct/2006
900RD015-10	S/USE RESUS KIT W/50mm MSK(10)	IIa	37498	Rule 2	24/Oct/2006
900RD016-10	S/USE RESUS KIT W/60mm MSK(10)	IIa	37498	Rule 2	24/Oct/2006
900RD101	GAS INLET ADAPTOR - 10 PACK	IIa	37498	Rule 2	29/Jun/2000
900RD110	S/USE RESUS HUMID W/O MSK 10PK	IIb	37498	Rule 9 scl 2	18/Aug/2004
900RD301	SIDE MOUNTING BLOCK	I	37075	Rule 1	04/Jun/1999
900RD302	WALL MOUNT BRACKET	I	37075	Rule 1	28/May/1999
900RD303	NEOPUFF RAIL BRACKET	I	37075	Rule 1	17/Apr/2002
BC513-01	Neopuff Ohmeda Assembly kit	I	37075	Rule 1	30/Oct/2008
RD020-01	TEST LUNG NON LATEX	I	12408	Rule 1	30/May/2007
RD050-01	NEOPUFF CENTRAL MTG BKT	I	37075	Rule 1	13/Apr/2004
RD1300-10	Kit Resus Adjustable 10	IIa	37498	Rule 2 scl 1	01/Oct/2010
RD1301-10	KIT RESUS ADJ GASLINE 10	IIa	37498	Rule 2 scl 1	29/Nov/2010
RD1330-10	KIT RESUS ADJ MSK 35mm	IIa	37498	Rule 2 scl 1	01/Oct/2010
RD1331-10	KIT RESUS ADJ MSK35 GASLINE 10	IIa	37498	Rule 2 scl 1	29/Nov/2010
RD1340-10	KIT RESUS ADJ MSK 42mm	IIa	37498	Rule 2 scl 1	01/Oct/2010
RD1341-10	KIT RESUS ADJ MSK42 GASLINE 10	IIa	37498	Rule 2 scl 1	29/Nov/2010
RD1350-10	KIT RESUS ADJ MSK 50mm	IIa	37498	Rule 2 scl 1	01/Oct/2010
RD1351-10	KIT RESUS ADJ MSK50 GASLINE 10	IIa	37498	Rule 2 scl 1	29/Nov/2010
RD1360-10	KIT RESUS ADJ MSK 60mm	IIa	37498	Rule 2 scl 1	01/Oct/2010
RD1361-10	KIT RESUS ADJ MSK60 GASLINE 10	IIa	37498	Rule 2 scl 1	29/Nov/2010
RD1370-10	KIT RESUS ADJ MSK 70mm	IIa	37498	Rule 2 scl 1	01/Oct/2010
RD1371-10	KIT RESUS ADJ MSK72 GASLINE 10	IIa	37498	Rule 2 scl 1	29/Nov/2010
RD800-EN	S/USE NEO MASK STARTER KIT	IIa	57824	Rule 2 scl 1	26/May/2006
RD800-SK	MASK ROUND STRTR KIT S/USE UNI	IIa	57824	Rule 2 scl 1	26/May/2006
RD803-10	S/USE NEO MASK 35MM 10BX	IIa	57824	Rule 2 scl 1	26/May/2006
RD804-10	S/USE NEO MASK 42MM 10BX	IIa	57824	Rule 2 scl 1	26/May/2006
RD805-10	S/USE NEO MASK 50MM 10BX	IIa	57824	Rule 2 scl 1	26/May/2006
RD806-10	S/USE NEO MASK 60MM 10BX	IIa	57824	Rule 2 scl 1	26/May/2006
RD807-10	S/USE NEO MASK 72MM 10BX	IIa	57824	Rule 2 scl 1	26/May/2006
RD900ADU	NEOPUFF INFANT RESUSCITATOR DA	IIb	13366	Rule 9 scl 2	14/Dec/1999

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RD900AEU	NEOPUFF INFANT RESUSCITATOR	IIb	13366	Rule 9 scl 2	21/Aug/1998
RD900AFU	NEOPUFF INFANT RESUSCITATOR FR	IIb	13366	Rule 9 scl 2	05/Feb/1999
RD900AGU	NEOPUFF INFANT RESUSCITATOR GE	IIb	13366	Rule 9 scl 2	12/Aug/1998
RD900ALU	NEOPUFF INFANT RESUSCITATOR IT	IIb	13366	Rule 9 scl 2	17/Nov/1998
RD900AMU	NEOPUFF INFANT RESUSCITATOR FI	IIb	13366	Rule 9 scl 2	14/Dec/1999
RD900ANU	NEOPUFF INFANT RESUSCITATOR NL	IIb	13366	Rule 9 scl 2	05/Feb/1999
RD900ASU	NEOPUFF INFANT RESUSCITATOR SP	IIb	13366	Rule 9 scl 2	09/Mar/1998
RD900ATU	NEOPUFF INFANT RESUSCITATOR PO	IIb	13366	Rule 9 scl 2	14/Dec/1999
RD900AVU	NEOPUFF INFANT RESUSCITATOR NO	IIb	13366	Rule 9 scl 2	23/Aug/1998
RD900AWU	NEOPUFF INFANT RESUSCITATOR SW	IIb	13366	Rule 9 scl 2	12/Dec/1998

GMDN Code	Term
12408	Lung simulator
13366	Automatic pneumatic pulmonary resuscitator, reusable
37075	General-purpose device mount
37498	Oxygen therapy system
57824	Resuscitator face mask, single-use